UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

AUG 28 2019

Michael G. Roberts, Pharm.D.
Radiation Safety Officer
Sofie Network, Inc. d/b/a SOFIE
21000 Atlantic Blvd.
STE. 730
Dulles, VA 20166

Dear Mr. Roberts:

We have reviewed your May 28, 2019 request to add a germanium-68/gallium-68 generator authorization to your NRC Radioactive Materials License, NRC License No. 24-32827-01MD. That letter omitted some information needed by our office prior to authorizing the use of germanium-68/gallium-68 generators, including no legally binding generator return agreement with a manufacturer or distributor of Galliapharm generators, no facility information regarding where the generators would be used or stored, no clarity as to the types of surveys the licensee will conduct for areas where the generators are used and stored, and no clarity as to whether the licensee wishes to have flexibility to update its program, with respect to germanium-68/gallium-68 generators.

As we discussed with your designated contact person, Michael Levy - via phone and email starting on August 7, 2019, additional information is needed from your company in order to complete our review of the application. To date, we have received no additional information in accordance with our request.

In accordance with our conversation, we have voided your request to add an authorization for the possession and use of germanium-68/gallium-68 generators, under the license. This action is without prejudice to resubmission. However, in resubmitting your request, please be reminded that Title 10 of the *Code of Federal Regulations* Sections 30.9 and 30.10 require that information provided to the Commission by a licensee to be complete and accurate in all material aspects. Deliberate submittal of incomplete or inaccurate information that is material to the Commission could subject the licensee to enforcement action.

If you have any questions in responding to this request, please call me at the Region III office at (630) 829-9892 so that our office may provide appropriate corrections and answers.

In accordance with 10 CFR Section 2.390, a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

Sara A. Forster

Sara A. Forster, M.S.
Health Physicist
Materials Licensing Branch

License No. 24-32827-01MD
Docket No. 030-38460